REMARKS

In the Final Action dated November 6, 2008, claims 92-115 are pending. Claims 114-115 are allegedly drawn to non-elected subject matter and are withdrawn from consideration. Claims 92-113 are examined and are rejected. Specifically, claim 103 is objected to for formality reasons. Claims 97-99 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 92-113 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with both the enablement requirement and the written description requirement. Claims 92 and 95-100 are rejected under 35 U.S.C. §102(b) as anticipated by Gauthier et al. (GenBank Sequence Accession No. U16794, published in 1995), taken with the evidence of Joshi et al. (*Plant Molecular Biology* 37: 663-674, 1998). Claims 92, 95-100 and 106-113 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Jorgensen et al. (U.S. Patent No. 5,034,323), in view of Joshi et al. and Jonsson et al. (*Planta* 160: 174-179, 1984). The Oath is also objected to as defective.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Telephone Interview

A telephone interview was conducted on January 21, 2009 with Examiner Stuart Baum, now assigned to this application. Applicants, through the undersigned, wish to thank Examiner Baum for the courtesy and helpful discussion during the interview. The §112, first paragraph rejections were discussed. In the following remarks, Applicants will identify the

support found in the specification and establish that the claims as presently amended fully satisfy the requirements of 35 U.S.C. 112, first paragraph.

Oath/Declaration

The Oath submitted on May 27, 2005 is defective because the alteration to the address of inventor "Ronald Koes" was not initialed.

Applicants provide herewith a supplemental Oath, which sets forth the correct address of Ronald Koes, and has been signed and dated by Ronald Koes. Further, the supplemental Oath sets forth the current address for inventor Linda Demelis, and has also been signed and dated by Linda Demelis. An updated Application Data Sheet is also provided herewith.

Withdrawal of the objection to the Oath is therefore respectfully requested.

Claim Objection

Claim 103 is objected to for reciting "mutant" instead of "material" in line 3.

Applicants have amended claim 103 to address the objection. Withdrawal of the objection is therefore respectfully requested.

35 U.S.C. §112, Second Paragraph

Claims 97-99 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for reciting "molecule" after "anthocyanin". The Examiner states that there is insufficient antecedent basis for the limitation "molecule".

Applicants have amended claims 97-99 to address the rejection. Withdrawal of the rejection is therefore respectfully requested.

35 U.S.C. §112, First Paragraph (Enablement)

Claims 92-115 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled. The Examiner acknowledges that the specification is enabling for a nucleotide sequence encoding a flavonoid methyltransferase (FMT) including the one defined in SEQ ID NO: 12, a genetic construct and a genetically modified plant comprising said nucleotide sequence. However, the Examiner contends that the specification does not reasonably provide enablement for a nucleotide sequence having about 70% or 95% identity to SEQ ID NO: 11, a nucleotide sequence encoding an amino acid having about 80% or 95% identity to SEQ ID NO: 12, or a nucleotide sequence capable of hybridizing under medium stringency conditions to a nucleotide sequence encoding SEQ ID NO: 12.

Applicants respectfully disagree.

In the first instance, Applicants draws the Examiner's attention to the fact that independent claims 92, 100 and 103 have been amended to replace "medium stringency" with "high stringency", the latter term being defined in the specification, e.g., on page 28, lines 7-10. Further, new claim 116 is added, which recite specific hybridization conditions as disclosed on page 59, lines 12-17 of the specification. New claim 117 depends from claim 92 and claim 116, and specifies the encoded enzyme to be 3'5' FMT.

Contrary to the Examiner's contention, Applicants respectfully submit that it would not take undue experimentation for those skilled in the art to make a nucleic acid molecule as presently claimed. Notably, as described in Example 9 (pages 72-77) of the specification, nearly 200,000 clones in the *Torenia* library were screened using a *Petunia* probe under low stringency conditions, and only 20 clones were tested positive. After sequencing, only one clone was

identified to be a desirable clone (SEQ ID NO: 11). Therefore, Applicants respectfully submit that the genus of nucleic acid molecules that would hybridize to SEQ ID NO: 11 under high stringency conditions, as presently claimed, are not so enormous to require undue experimentation. The fact that those skilled in the art were able to isolate the *Torenia* clone comprising SEQ ID NO: 11 by using a probe from a related *Petunia* molecule is evidence that the additional experimentation that would be required, if any, is ***not undue*** in order to obtain a nucleic acid molecule as claimed.

It is further noted that an FMT-encoding clone was also isolated from *Fuchsia* based on similar hybridization approach, as disclosed in Example 12 (pages 100-105) of the specification. This *Fuchsia* FMT molecule shows 82% amino acid similarity to SEQ ID NO: 12 (*Torenia*). The isolation of the FMT-encoding clone from *Fuchsia* is also evidence that those skilled in the art would be able to obtain a nucleic acid molecule as claimed, without undue experimentation.

Moreover, those skilled in the art would also be able to determine whether the encoded protein is an FMT enzyme that methylates anthocyanins, without undue experimentation. The specification describes a number of assays for identifying an FMT enzyme that methylates anthocyanins using delphinidin 3-glucoside, delphinidin 3,5-diglucoside or delphinidin 3-rutinoside by expressing the isolated cDNA clones in an E. coli expression system. See Example 7 (pages 61-67), Tables 10 and 11; Example 9 (pages 72-77), Tables 15-16; and Example 10 (pages 78-81), Tables 17-18 of the specification. Furthermore, the specification discloses how to confirm the methyltransferase activity of the isolated FMT via expression in a plant such as rose. See Example 11 (from page 82 on), and the results provided in Tables 21-23.

Accordingly, Applicants respectfully submit that those skilled in the art would be able to isolate a nucleic acid that hybridizes to SEQ ID NO: 11 or that shares a required sequence homology to SEQ ID NO: 11 or 12, and further determine whether the encoded protein methylates anthocyanins, without undue experimentation. Reconsideration and withdrawal of the enablement rejection are respectfully requested.

35 U.S.C. §112, First Paragraph (New Matter)

Claims 92-113 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner alleges that the specification does not support the following phrases previously introduced to the claims: "70% identity after optimal alignment to SEQ ID NO: 11", "95% identity after optimal alignment to SEQ I DNO: 11" (claims 93, 101 and 104), "80% identity after optimal alignment to SEQ ID NO: 12" (claims 92, 100 and 103) and "95% identity after optimal alignment to SEQ ID NO: 12" (claims 94, 102 and 104).

Applicants respectfully submit that the term "after optimal alignment" finds support in the specification, e.g., page 30, lines 2-3. Further, those skilled in the art would understand that comparison of sequences is typically premised on an optimal alignment.

Further, in referencing SEQ ID NO: 12, claims 92, 100 and 103 recite the term "similarity", rather than "identity" as the Examiner has indicated. The Examiner does not dispute that the specification provides support for the term "similarity", for example, on page 27, lines 12-14; page 28, lines 19-23; and page 32, lines 18-19.

Moreover, the Examiner indicates that the specification discusses "similarity", not "identity" as recited. Applicants direct the Examiner's attention to page 28, lines 25-26, where it

is stated that the term "similarity as used herein includes exact identity between compared sequences…".

Accordingly, it is respectfully submitted that the present claims are fully supported by the specification and do not introduce new matter. Withdrawal of the new matter rejection is respectfully requested.

35 U.S.C. §112, First Paragraph (Written Description)

Claims 92-113 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. More specifically, the Examiner is of the opinion that there is no description of the structure required for the recited function (being an FMT that methylates anthocyanins), and no description of the common attributes that identify members of the genus as claimed.

Applicants respectfully disagree.

Under the Guidelines for the Examination regarding the written description requirement, possession of the invention may be shown by describing the invention with sufficiently detailed, relevant identifying characteristics, i.e., complete or partial structure, physical and/or chemical properties, correlation between structure and function, or some combination thereof. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics, and the method of making the invention. The Guidelines also provide that the written description requirement may be satisfied through sufficient description of a representative number of species within the claimed genus.

In the present case, the specification has adequately described relevant identifying characteristics of the genus. Structurally, the nucleic acids within the genus either hybridize to a specified sequence under high stringency conditions (claims 92-113) or specific stringent conditions (116-117), or share specified sequence homology to SEQ ID NO: 11 (or SEQ ID NO: 12). Functionally, the nucleic acids within the genus are defined as encoding an FMT that methylates anthocyanins. The specification has also provided ample examples for how to determine whether the encoded protein is an FMT enzyme that methylates anthocyanins, as discussed above.

Moreover, the application discloses several FMT-encoding clones from various plants, including from *Petunia* (SEQ ID NOS: 4 and 6), from *Torenia* (SEQ ID N: 11), and from *Fuchsia* (SEQ ID NO: 21). See page 14, for example. The encoded FMT proteins share significant sequence similarities (approximately 80%), as disclosed in page 72 and page 105 of the specification. It is further noted that the specification also demonstrates that the *Petunia* and *Torenia* proteins were able to methylate anthocyanins. See Example 7 (pages 61-67), Tables 10 and 11; Example 9 (pages 72-77), Tables 15-16; and Example 10 (pages 78-81), Tables 17-18 of the specification.

Accordingly, Applicants respectfully submit that the specification has adequately described relevant identifying (structural and functional) characteristics of the genus, and has also described a representative number of species. Accordingly, Applicants respectfully submit that the present claims fully satisfy the written description requirement. Reconsideration and withdrawal of the written description rejection are respectfully requested.

Prior Art Rejections

Claims 92 and 95-100 are rejected under 35 U.S.C. §102(b) as anticipated by Gauthier et al. (GenBank Sequence Accession No. U16794, published in 1995), taken with the evidence of Joshi et al. (*Plant Molecular Biology* 37: 663-674, 1998). Claims 92, 95-100 and 106-113 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Jorgensen et al. (U.S. Patent No. 5,034,323), in view of Joshi et al. and Jonsson et al. (*Planta* 160: 174-179, 1984).

According to the Examiner, both the §102(b) and §103 rejections are made because the Examiner contends that the "medium stringency conditions" recited in claims 92 and 100 would encompass hybridization of a nucleotide sequence having low homology to a nucleotide sequence encoding SEQ ID NO: 12, and encoding a functional flavonoid methyltransferase. Therefore, the Examiner assumes that the cDNA sequence disclosed by Gauthier et al. and the cDNA sequence disclosed by Joshi et al. would be able to hybridize under "medium stringency conditions", recited in instant claims 92, 100 and 103, to a nucleotide sequence (including SEQ ID NO: 11) encoding instant SEQ ID NO: 12.

As submitted above, independent claims 92, 100 and 103 have been amended to replace "medium stringency" with "high stringency", the latter term being defined in the specification, e.g., on page 28, lines 7-10. Further, new claim 116 is added, which recite specific hybridization conditions as found on page 59, lines 12-17. New claim 117 depends from claim 92 and claim 116.

Applicants respectfully submit that there is no evidence or indication showing that the nucleic acid molecules disclosed by Gauthier et al. or Joshi et al. would hybridize to the specified sequence under the conditions presently recited in the claims. At least the Examiner has not met

his burden to establish this. In fact, compared to the *Torenia* FMT molecule (SEQ ID NOS: 11 and 12), *C. americanum* MT (U16794) of Gauthier et al. has 9% identity and overall 20% similarity at the amino acid level, and 51% identity at the nucleotide level. When examining the pairwise alignment, there are very limited stretches of identical nucleotides, suggesting that the clone of Gauthier et al. would not hybridize under the conditions specified in the present claims.

Further, Applicants respectfully submit that the present application provides for the first time nucleic acid molecules that encode an FMT that has the ability to methylate anthocyanins. The enzymes encoded by the prior art nucleic acid molecules do not have the ability to methylate anthocyanins, which is a function of the encoded protein required by the present claims. In support of Applicant's position in this regard, it is noted that on page 243 of Gauthier et al., the authors state that

- "plant OMTs have been shown to possess *narrow* substrate specificities" (right coln.);
- the cDNA clones act on the flavonoid aglycones, luteolin and quercetin and caffeic and hydoxyferulic acids (abstract);
- specifically targettig the lignin pathway.

Accordingly, the premise for the Examiner's §102(b) and §103 rejections is invalid. The cDNA sequences disclosed by Gauthier et al. and by Joshi et al. would not hybridize under the recited conditions to SEQ ID NO: 11, and do not encode an FMT that methylates anthocyanins. Therefore, reconsideration and withdrawal of the §102(b) and §103 rejections are respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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